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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/630,884

07/30/2003

Kazunori Taniguchi

P/3541-39

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

08/21/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/630,884 | <b>Applicant(s)</b><br>TANIGUCHI ET AL. |  |
|                              | <b>Examiner</b><br>LINDSEY BACHMAN   | <b>Art Unit</b><br>3734                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4,5,7-17,19-28,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,5,7-17,19-28,33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

This Office Action is in response to Applicant's amendment filed 29 October 2008.

### ***Response to Arguments***

Applicant's arguments filed 29 October 2008 have been fully considered but they are not persuasive.

Regarding Applicant's arguments that open and closing of the end effector is not rotation. Examiner maintains the arguments regarding this, as stated in the Office Action mailed 29 May 2008. It is suggested that Applicant more specifically claim the type of rotation intended.

Applicant's arguments state that element 11 of Hashiguchi (identified by the Examiner as the extended portion) is not an extended portion disposed in the end of the elongate member (identified as by the examiner as element 29). This is not persuasive because element 11 is clearly shown as being inside of element 29 in Figures 4a, 4b. Further, element 11, especially 11a and 11b, limit the amount that the end effectors can open and close as shown in Figures 4a and 4b. The claim recitation that the extended portion is "disposed in" the elongate member does not require that the extended portion is a part of the elongate member; the Examiner is interpreting this limitation to mean that that the extended portion is "arranged" in the elongate member, which is cited as the definition of "disposed" in the Merriam Webster Dictionary Online.

Regarding the argument that the base member (8) is not surrounded on at least one side by the extended portion, this is not persuasive as is clearly shown in at least Figures 2b, 4a.

The rejection under 35 USC 103 over Hassler in view of JP 5-245153 has been withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4-5, 7-17, 19-28, 33 and 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant claims that the insertion section is rotatable from a first position to a second position at a predetermined angle relative to the axis of the insertion section. Applicant does not disclose the rotation of sheath to any particular angle in the specification.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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Claim 4 states that the extended portion and sheath are part of an insertion section on line 14-15. Lines 16-17 go on to state that the sheath is rotatable relative to the insertion section. It is not clear how the sheath can be rotatable relative to the insertion section since Applicant previously stated the sheath is part of the insertion section. Further, Claim 4 states that the extended portion is integral with the sheath/elongate member on line 13-14, but on line 10 Applicant states that the extended portion is located in the distal end of the elongate member. It is not clear how something can be located inside of something and also be integral.

Regarding Claims 17 and 34, it is unclear how the sheath can be attached/detached from the insertion section since lines 14-15 of Claim 4 state that the sheath is part of the insertion section.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the limitations of Claim 4, specifically regarding the arrangement of the sheath with respect to the insertion portion as addressed in the 35 U.S.C. 112, first paragraph rejection must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

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number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 4, 5, 7, 9, 10, 19, 23-25 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashiguchi (US Patent 6,063,103) in view of Yates et al. (US Statutory Invention Registration H1,904).**

Claim 4: Hashiguchi'103 discloses a device that contains an end effector (4, 5), a support (14) having a proximal end which supports the end effector (see Figures 4a, 4b), a base member (8) having a distal (8a) and proximal end. The base member pivotally supports the proximal end of the support (see Figure 4b) to enable the end

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effector and the support to be rotated together with respect the base member. The device also contains an elongate member (sheath 29) with a distal end at which the base member is located (see Figure 4b) and an extended portion (11) disposed in the distal end of the elongate member to prevent forward and backwards motion of the base member with respect to the support (see Figure 4a, 4b) and cover at least one side of the base member (see Figures 3a-3c).

Hashiguchi'103 does not teach a sheath that prevents the end effector from moving in any direction when moved from a first to a second position.

Yates'904 teaches a device with an end effector (32) and a sheath (38), in which the sheath can be rotated to orient the end effector. The orientation of the sheath orients the end effector in a particular direction; depending on the orientation of a knob (15), which controls the sheath (38), the end effector can not be oriented in all directions (column 7, lines 48-53). It would be obvious to modify the device of Hashiguchi'103 with the knob/sheath combination of Yates'904 in order to control the orientation of the distal end effector without having to reorient the handles as well.

Claim 5: Hashiguchi'103 teaches the extended portion (11) has an annular distal surface (11a) that is inclined (perpendicular to) relative to the longitudinal axis of the sheath (see Figure 1-4).

Claim 7: Hashiguchi'103 teaches the sheath and the extended portion are rigid (see Figure 1).

Claim 9: Hashiguchi'103 teaches the sheath is a circular tube shape (Figure 4a, 4b) and the proximal end of the extended portion is formed as a notch in the circular

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tube shape with the bottom portion of the notch extending along a plane that includes the central axis of the sheath (see portion of element 11, between 11 and 11a in Figure 4a or 4b).

Claim 10: Hashiguchi'103 teaches the sheath is a circular tube shape (Figure 4a, 4b) and the extended portion orthogonal to the sheath (11a) has a circular arc shape (see Figure 4a).

Claim 19: Hashiguchi'103 teaches an end effector operation section (9a) and a rotation operation section (9b).

Claim 23: Hashiguchi'103 teaches that the support is a pivot and the end effector is supported by the pivot (see Figure 4a, 4b).

Claim 24: Hashiguchi'103 teaches the end effectors are jaws (see Figure 4a, 4b) which are supported by the pivot and are relatively rotated by using the pivot as a rotary axis (see Figures 4a, 4b).

Claim 25: Hashiguchi'103 discloses an end effector operation section (9a) and a rotation operation section (9b).

**Claim 8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashiguchi'103 in view of Yates'904, as applied to Claims 4 and 7, in further view of Miyawaki, et al. (US Patent 6,066,151).**

Claim 8 and 11: Hashiguchi'103 in view of Yates'904 do not teach the combination of a conductive end effector arms with an insulating outer tube.

Miyawaki'151 teaches that the elongate member and the end effector have conductive areas to apply high frequency power to the end effector (column 5, lines 16-



19, column 6, lines 33-56, and column 8, lines 45-51). Further, the sheath has an inner tube and an insulating outer tube (column 5, lines 16-19). It would have been obvious to one skilled in the art to modify the device taught by Hashiguchi'103 by applying high frequency power as taught by Miyawaki'151 in order to aid in cutting body tissue. Further, it would be obvious to use an insulated sheath to protect the body areas not being treated from the power.

**Claims 12, 13, 14, 20-22 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashiguchi'103, as applied to Claim 4 and 19, in further view of Lee'844.**

Claim 12: Hashiguchi'103 teaches the limitations of Claim 12, except for an operation section that rotates the end effector and first and second driving members.

Lee'844 discloses a device that contains an end effector (602, 603); a support (601) in which the proximal end (towards 626) supports the end effector; a base member (600) which pivotally supports (around axis 604/pin 620) the proximal end of the support on its distal end (towards 620) so that the support can rotate along with the end effector (see Figure 3a). The device also contains an extended portion (300, 302, 303) that has a proximal end and a distal end; the base member is attached to the distal end of the extended portion. Further, the extended portion prevents forward and backward rotation of the base member with respect to the support and the extended portion covers at least one side (the proximal portion) of the base member.

Further, Lee'844 teaches an operation section (300, 302, 303) that rotates the end effector and the support (column 8, lines 32-42) (The operation section contains

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wheels 330, 332, 334 that are connected to cables 606-609. The cables rotated the end effector and the support.). The insertion section has first (608, 609) and second (606, 607) driving members that are arranged side by side (in portion 302, 303). The first driving members operate the end effector (column 6, lines 33-53) and the second driving members operate the support (column 6, lines 22-33). It would have been obvious to one skilled in the art at time the invention was made to modify the device taught by Hashiguchi'103 with an operation section in order to increase movement of the device and increase the range of motion of the end effector.

Claim 13: Hashiguchi'103 teaches that teaches that the end effectors are a pair of jaws and the jaws are supported by the support. Hashiguchi'103 does not teach that the support is connected to the distal end of a driving member.

The end effectors taught by Lee'844 are a pair of jaws that can be opened and closed (Figure 3a). The jaws are supported by the support (at 624) (Figure 3b). The support is connected to the distal end of the second driving member to rotate the support in one plane (see Figure 3a, 3b, and arrow J5). It would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by Hashiguchi'103 with the modifications taught by Lee'844 in order to increase the movement of the device and increase the range of motion of the end effector.

Claim 14: Hashiguchi'103 does not teach a sliding member or a connection member.

Lee'844 teaches a sliding member (610, 611) that is supported by one jaw (Figure 3b) and slid to open/close the jaws (column 6, lines 33-54). There is connection member (round base, as shown in Figure 3b that supports the cables 610, 611. Round base cannot be seen in Figure 3b for cables 610, 611, see equivalent around 608, 609.). The connection member is connected to the sliding member (see Figure 3b) and the distal end of the first driving member (608, 609) (when the device is assembled (see Figure 3a). It would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by Hashiguchi'103 with the sliding member taught by Lee'844 because it helps open and close the jaws.

Claim 20 and 21 and 26 and 27: Hashiguchi'103 teaches the limitations of Claim 20, 21 and 26 except for a first and second transmitting member.

Lee'844 discloses a first transmitting member (608-611) that has distal and proximal ends. The proximal end is dynamically connected to the end effector operation section (332, 334) (column 8, lines 32-42 and Figure 4) and the distal end is dynamically connected to the end effector (see Figure 3b). There is also a second transmitting member (606, 607) in which the proximal end is connected to the rotation operation section (330) (column 8, lines 32-42 and Figure 4) and the distal end is connected to the support (601) (column 8, lines 27-33). Lee'844 teaches the first transmitting member has a first part (proximal end) disposed in the elongate member (column 8, lines 32-43) and a second part (distal end) disposed in the support (601) (near element 630 in Figure 3b). It would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by Hashiguchi'103 with a

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first and second transmitting member, as taught by Lee'844 in order to maximize control of the distal end section.

Claim 22 and 28: Hashiguchi'103 teaches that the elongate member is a sheath. Further, it is inherent that if the device taught by Lee'844 were modified with a sheath over sections 302, 303, the first and second transmitting members would pass through it. It would have been obvious to one skilled in the art at the time the invention was made to modify extended portion taught by Lee'844 by covering it with a sheath as taught by Hashiguchi'103 in order to aid in inserting the endoscopic portion of the device into the body, as is well known in the art.

**Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashiguchi'103 in view of Yates'104 in view of Lee'844, as applied to Claim 12, in further view of Miyawaki, et al. (US Patent 6,066,151).**

Hashiguchi'103 teaches an insulating sheath (column 4, lines 54-55). Hashiguchi'103 does not teach a conductive first driving member (608, 609).

Miyawaki'151 teaches that the elongate member and the end effector have conductive areas to apply high frequency power to the end effector (column 5, lines 16-19, column 6, lines 33-56, and column 8, lines 45-51). It would be obvious to make the member that moves the end effector (first driving member) conductive as well because the power needs to be transmitted from the proximal end of the device to the distal treating end of the device. Further, the sheath an insulating outer tube (column 5, lines 16-19). It would have been obvious to one skilled in the art to modify the device taught by Lee'844 by applying high frequency power as taught by Miyawaki'151 in order to aid

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in cutting body tissue. Further, it would be obvious to use an insulated sheath to protect the body areas not being treated from the power.

**Claim 17 and 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hashiguchi'103 in view of Yates'104, as applied to Claim 4, in view of Miyawaki'151.**

Claim 17 and 34: Hashiguchi'103 in view of Lee'844 does not teach an attaching/detaching mechanism.

Miyawaki'151 teaches an attaching/detaching mechanism (32, 33) in order to remove the sheath (column 4, line 62 to column 5, line 6). It would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by Hashiguchi'103 in view of Lee'844 by adding a attaching/detaching mechanism to the sheath in order to remove it after use for cleaning/replacement.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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